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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,372	09/22/2003	Isabelle Nonotte	016800-643	5014
21839	7590	04/03/2006		
BUCHANAN INGERSOLL PC (INCLUDING BURNS, DOANE, SWECKER & MATHIS) POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404				
			EXAMINER GOLLAMUDI, SHARMILA S	
			ART UNIT 1616	PAPER NUMBER

DATE MAILED: 04/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/665,372	Applicant(s) NONOTTE ET AL.	
	Examiner Sharmila S. Gollamudi	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,6,7,9-11,13-15,17-19,21,45-48,50-61,68 and 69 is/are pending in the application.
- 4a) Of the above claim(s) 5,38,39,41-44,49 and 62-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6,7,9-11,13-15,17-19,21,45-48,50-61,68 and 69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/859,392.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of Response to the Restriction Requirement, Amendments/Remarks, and the Information Disclosure Statement filed 1/3/06 is acknowledged. Claims **1-2, 6-7, 9-11, 13-15, 17-19, 21, 45-48, 50-61, 68-69** are pending in this application. Claims 5, 38-39, 41-44, 49, 62-67 are withdrawn as being directed to a non-elected invention. Claims 3-4, 8, 12, 16, 20, 22-37, and 40 stand cancelled.

Election/Restrictions

Applicant's election with traverse of Group I and the species hydroxy acids in the reply filed on 1/3/06 is acknowledged. The traversal is on the ground(s) that the fields of search would be coextensive and the search of both groups would not be an undue burden on the examiner. This is not found persuasive because as extensively discussed in the Office Action of 11/2/05, the search is not coextensive since the composition may be used for a materially different process and the process for using the composition may be practiced with a materially different product. Thus, applicant's arguments are not persuasive and the search is not necessarily coextensive.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

The information disclosure statement filed 9/22/03 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document (JP 403017004A); each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 48, 56-61, and 69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 48 is directed to a method of combating skin pallor comprising administering an effective amount of manganese and a bioaffecting amount of at least one member from the group consisting of alverine, alverine salts, keratolytic agent, chlorine-channel openers, hydroxy acids, and retinoids, wherein manganese is the sole ingredient for treating skin pallor. The claim is vague and indefinite since the claim has two contradictory limitations. For instance, the claim requires that only manganese is the sole active agent for combating skin pallor; however keratolytic agents such as salicylic acids have the capability of also combating skin pallor. Further, alverine and chlorine channel opener act as muscle relaxants and would thus treat skin pallor by relaxing the vasoconstriction of the blood allowing; thereby allowing blood circulation. Therefore, the metes and bounds of the claim are unclear.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 9, 13, 17, 21, 47, 52, and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 04108710 to Shiga (abstract only).

Shiga discloses particles of a demagnetized ferromagnetic material such as magnetite or Manganese zinc ferrite dispersed in a medium. Preferably the medium is a dispersion medium selected from a film-forming polymeric viscous substance and a gel-forming montmorillonite or an oil and fat. The dispersion promotes blood flow important for the health of the skin. See abstract. Note it is the examiner's position that a composition that is utilized for increasing microcirculation will implicitly treat skin pallor since skin pallor is caused by the lack of blood flow; thus increasing blood flow will decrease skin pallor.

Claims 1-2, 6-7, 13-15, 21, 47, 50-51, and 55 are rejected under 35 U.S.C. 102(e) as being anticipated by Pauly (6,274,123).

Pauly discloses a composition for cosmetic, dermatologic, or pharmaceutical applications, of a plant extract of the genus *Adansonia*, particularly of the species *Adansonia digitata* (baobab) for the skin and/or the hair, eyelashes or nails. See abstract. Baobab leaves contain high quantities of calcium (3.07 to 30 mg/g of dry leaves) and substantial quantities of iron, potassium, magnesium, manganese, molybdenum, phosphorus and zinc. See column 1, lines 50-55. Pauly discloses the extraction process of baobab provides for a directly usable fraction rich in flavonoids, mineral salts, proteins, vitamins and/or other like compounds, such as particularly tannins. See column 2, lines 55-60. The composition comprise between 0.01% and 20.00% by weight of extract, particularly extract of leaves of baobab (manganese-rich plant). See column 5, lines 1-10.

Art Unit: 1616

Specifically Pauly discloses an anti-wrinkle, anti-free radical, anti-skin aging cream that improves microcirculation comprising 2% of the flavonoidal extract of *Adansonia digitata*. Note the flavonoid extract is defined as a rich fraction is flavonoids, mineral salts, proteins, vitamins, and like compounds. See column 2, lines 60-66. Also the other ingredients in the composition fall within instantly claimed “physiologically acceptable alcohols, oils, fatty acids, waxes, emulsifiers, hydrophilic gelling agents, lipophilic gelling agents, preservatives, antioxidants, fragrances, fillers, UV-screening agents, dyestuffs, colorants, keratolytic agents, alverine, alverine salts, chlorine-channel openers, hydroxy acids and retinoids”. Note it is the examiner’s position that a composition that is utilized for increasing microcirculation will implicitly treat skin pallor since skin pallor is caused by the lack of blood flow; thus increasing blood flow will decreases skin pallor.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 6-7, 9-11, 13-15, 17-19, 21, 45-48, 50-61, and 68-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Breton et al (5,900,257) by itself or in further view of Questions and Answers About Raynaud’s Phenomenon distributed by the National Institute of Arthritis and Musculoskeletal and Skin Diseases.

Breton teaches a cosmetic, dermatological or pharmaceutical compositions comprising at least one lanthanide, manganese, tin or yttrium salt as a substance P antagonist for the treatment

Art Unit: 1616

of disorders associated with an excessive synthesis and/or release of substance P and for the treatment of sensitive skins. See abstract. Breton teaches substance P is involved in the transmission of pain and in diseases of the central nervous system including skin disorders and vasospastic disorders (for example, migraine, Raynaud's disease). See column 1, lines 35-60 and especially lines 54-55.

Breton teaches the at least one lanthanide, manganese, tin or yttrium salt is formulated into a cosmetic or dermatological or pharmaceutical composition for the treatment of disorders of the central nervous system, allergic syndromes, inflammation, pain, gastrointestinal disorders, skin disorders, fibrosis, collagen maturation disorders, cardiovascular disorders, vasospastic disorders, immunological disorders, as well as disorders of the urinogenital tract, ophthalmic and pancreatic disorders. See column 2, lines 35-50.

In the field of skin or cutaneous disorders, Breton teaches it is known that certain skins are more sensitive than others. Breton teaches sensitive skins could be divided into two main clinical forms, irritable and/or reactive skins and intolerant skins. An irritable and/or reactive skin is a skin which reacts through itching or through pricking in reaction to various factors including the environment, *emotion*, food, the wind, rubbing, shaving, soap, surfactants, hard water with a high concentration of calcium, *temperature variations* or wool. An intolerant skin is a skin which reacts, through sensations of warming inflammation, stabbing pain, pins and needles and/or reddening, to various factors such as the environment, emotions, etc. See column 3.

The lanthanide, manganese, tin, or yttrium salt are formulated in an amount ranging 10^{-5} to 20%, preferably from 0.5% to 8% of the total weight of the composition and the salts form

Art Unit: 1616

may be selected from carbonates, bicarbonates, sulfates, glycerophosphates, borates, chlorides, nitrates, acetates, hydroxides, and persulfates. See column 4, lines 40-65.

Breton teaches for topical application the composition is formulated into emulsions, liquids, gels, creams, etc. See column 5, lines 1-15. Additional active agents that are utilized in the composition include keratolytic agents, i.e. hydroxy acids (glycolic acid, lactic acid, salicylic acid, citric acid, fruit acids, and n-octanoyl-5-salicylic acid). See column 7, lines 15-25. Breton discloses that exemplary active agents include hydroxyl acid. See column 7, lines 65-67.

Specifically example 3 teaches a care cream comprising 15% manganese chloride, 2% glycerol (physiologically acceptable alcohol), methyl paraben (preservative), perfume, and water.

Breton does not exemplify the method of treating vasospastic disorders.

Although Breton does not specify treating vasospastic disorders including Raynaud's phenomenon, it is would have bee obvious for a skilled artisan at the time the invention was made to look to the guidance provided by Breton and utilize the manganese formulation to treat a vasospastic disorder which would in turn treat skin pallor. One would be motivated to do so since Breton teaches salts including manganese are utilized in treating disorders wherein substance P is involved since the salts (manganese) act as substance P antagonists and thus the salts may be used to treat vasospastic disorders. Vasospastic disorders are characterized as the persistent contraction of blood vessels, which reduces blood flow in the vessels. Therefore, if a skilled artisan treated a vasospastic disorder by increasing the blood flow utilizing the substance P antagonist, then is obvious skin pallor will be treated since skin pallor is caused by the lack of blood circulation.

Art Unit: 1616

Furthermore, it is would have bee obvious for a skilled artisan at the time the invention was made to combine the teaching of Breton and the pamphlet on Raynaud's Phenomenon and expect to treat skin pallor (skin pallor caused by stress) by utilizing Breton's composition comprising manganese. The pamphlet teaches Raynaud's Phenomenon is a vasospastic disorder which is characterized by episodic attacks called vasospastic attacks that cause the blood vessels to constrict and during the attack the skin changes color from pallor wherein the skin turns white due to the lack of blood flow. Further, the pamphlet discloses stress, temperature, and emotional upsets trigger the attacks. Therefore, a skilled artisan would have expected to treat skin pallor by utilizing Breton's manganese composition since firstly Breton suggests the use of the manganese composition to treat vasospastic disorders such as Raynaud's Phenomenon and secondly the pamphlet on Raynaud's Phenomenon states that Raynaud's is a vasospastic disorder that is characterized by skin pallor and triggered by emotional or physical stress.

Conclusion

All the claims are rejected at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1616

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
Examiner
Art Unit 1616

